NOVABONE
SYNTHETIC BONE GRAFT PRODUCTS

K053387

FEB 14 2006

**510(k) Summary** **12/01/05**

**PerioGlas - Bone Graft Particulate**

**1. Submitter Information:**

| | |
|---|---|
| Name: | NovaBone Products, LLC |
| Address: | 13709 Progress Boulevard, #33<br>Alachua, FL 32615 |
| Telephone: | (386) 462-7660 |
| Facsimile: | (386) 418-1636 |
| Contact: | David M. Gaisser |

**2. Name of Device:**

| | |
|---|---|
| Trade Name: | PerioGlas – Bone Graft Particulate |
| Common Name: | Osteoconductive Bone Void Filler<br>Synthetic Resorbable Bone Graft Material |
| Classification Name: | Endosseous Implant for Bone Filling and/or Augmentation |

**3. Legally Marketed Predicate Device:**

| | |
|---|---|
| Predicate #1: | PerioGlas – Synthetic Bone Graft Particulate<br>[K040278, K992416, K962492, K930115]<br>(Also named as NovaBone per Special 510(k) K000149) |
| Predicate #2: | NovaBone – Resorbable Bone Graft Substitute<br>[K052494, K021336] |

**4. Device Description**

PerioGlas is a one-component resorbable bone void filler composed of a synthetic calcium phospho-silicate (Bioglass) particulate designed specifically for its absorbability and osteoconductive nature. The device is intended for dental intraosseous, oral, and cranio-/maxillofacial bony defects. It is supplied sterile. At time of use, the device is mixed with sterile water, saline, the patient's own blood or marrow, or with autogenous or allograft bone to form a wet sandy paste that is applied to the defect. PerioGlas is progressively resorbed and replaced by new bone tissue during the healing process.

**5. Intended Use**

PerioGlas is indicated to be packed into bony voids or gaps to fill and/or augment oral, dental intraosseous, and craniofacial defects. These defects may include: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant

preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. PerioGlas may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either as a bone graft extender.

## 6. Technological Characteristics

The device is designed as an osteoconductive space-filling particulate device to be gently packed into defect sites and used as a non-structural scaffold for the body's natural healing and bone regeneration process. The device acts as a particulate, synthetic, inorganic, biocompatible and osteoconductive material.

PerioGlas is a single-phase bioactive glass (45S5 Bioglass) particulate device. No changes to the device or its indications have been made with this submission. The purpose of this premarket notification is to expand the product claims to cover the claim of the device being osteostimulative. After implantation, surface reactions result in the absorption of the device material and concurrent new bone tissue formation. These surface reactions result in an osteostimulative affect, defined as the stimulation of osteoblast proliferation and differentiation during *in vitro* osteoblast cell culture studies as evidenced by increased DNA content and elevated osteocalcin and alkaline phosphatase levels.

## 7. Complications

No modifications have been made to the PerioGlas device. Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery. Complications specific to oral/dental use are those as may be typically observed for similar bone grafting procedures and may include: tooth sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, abscess formation

## 8. Conclusion

PerioGlas functions as a bone void filler for non-structural osseous defects. *In vivo* study data were presented supporting a superior rate of osteconduction and bone formation at early post-implantation periods compared to hydroxyapatite devices. *In vitro* cell culture data were presented to demonstrate and define the osteostimulative nature of the PerioGlas device. The addition of this claim does not modify the characteristics of the device, which has not been modified for this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2006

Mr. David M. Gaisser
VP Operations
Novabone Products, LLC
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K053387
Trade/Device Name: Perioglas Bone Graft Particulate
Regulation Number: 21 CFR 872.3930
Regulation Name: Tricalcium phosphate granules for dental bone repair
Regulatory Class: II
Product Code: LYC
Dated: December 1, 2005
Received: December 9, 2005

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

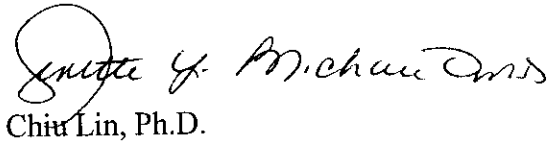
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033387

# STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: PerioGlas - Bone Graft Particulate

Indications For Use:

The intended use of PerioGlas is to provide a safe, biocompatible synthetic bone graft material for use in oral, dental intraosseous, and craniofacial defects. It is used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (Demineralized Freeze Dried Bone) or may be mixed with either (typically 1:1 ratio v/v) as a bone graft extender. Typical uses include:

- Periodontal/Infrabony defects
- Ridge Augmentation (sinusotomy, osteotomy, cystectomy)
- Extraction sites (ridge maintenance/augmentation, implant preparation/ placement)
- Sinus lifts
- Cystic cavities
- Cranio-facial augmentation

For larger defects, a mixture of PerioGlas® with an equal volume of allograft or autograft bone and bone marrow may improve new bone formation.

Prescription Use XX OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

(510(k) Number) K033387